

Attorney Docket No.: PTQ-0028  
Inventors: Van Eyk et al.  
Serial No.: 09/419,901  
Filing Date: October 18, 1999  
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#### REMARKS

Claims 1-7, 16-18, 20-28, 31, 34, 35 and 37-41 are pending in the instant application. Claims 1-7, 16-18, 20-28, 31, 34, 35 and 37-41 have been rejected. Reconsideration is respectfully requested in light of the following remarks.

#### **I. Provisional Obviousness-type Double Patenting Rejection**

Claims 1-7, 16-18, 20-28, 31, 34-35 and 37-41 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 80-98 of copending U.S. Application No. 09/115,589.

Claims 37 and 39 have also been rejected under the judicially created doctrine of obviousness-type double patenting over claims 80-98 of copending U.S. Application No. 09/115,589 in view Jideama et al. (Journal of Biological Chemistry, Vol. 271, No. 38, 9/20/96, 23277-23283).

Applicants respectfully disagree as the invention claimed in the instant application is clearly novel and unobvious over the invention of U.S. Application No. 09/115,589.

However, in an earnest effort to advance the prosecution of this case, Applicants are filing herewith a

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terminal disclaimer with respect to U.S. Application No.  
09/115,589.

Withdrawal of these rejections is therefore  
respectfully requested.

## **II. Rejection of Claims under 35 U.S.C. 103(a)**

Claims 1, 16-18, 20-27, 31 and 34 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Lofberg et al. (Archives of Neurology, Vol. 52, 12/1995, pages 1210-1214) in view of Solaro et al. (Journal of Molecular Cell Cardiology, Vol. 28, pages 217-230, 1996) and Lin et al. (The Journal of Biological Chemistry, Vol. 271, No. 1, 1/5/1996, pages 244-249) and further in view of Han et al. (International Journal of Biochemistry, Vol. 24, No. 1, 1992, pages 19-28).

Claims 2-7, 28, 34-35, 38 and 40-41 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Lofberg et al. in view of Solaro et al. and Lin et al. and further in view of Han et al. as applied to claims 1, 16-18, 20-27 and 34 above, and further in view of Wicks et al. (U.S. Patent 5,834,220).

Claims 37 and 39 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Lofberg et al. in view of

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Solaro et al. and Lin et al. and further in view of Han et al. and Wicks et al. (U.S. Patent 5,834,220) as applied to claims 2-7, 28, 34-35, 38 and 40-41 above, and further in view of Jideama et al. (The Journal of Biological Chemistry, Vo. 271, No. 38, 9/20/96, pages 23277-23283).

Applicants respectfully traverse these rejections.

The Examiner has acknowledged by her withdrawal of rejections set forth in the Office Action mailed October 11, 2006 that the combined teaching of Solaro et al., Lin et al. and Han et al. with or without Wicks et al. and/or Jideama, do not render obvious the instant claimed invention. See page 13, paragraph 7 of the Office Action mailed May 2, 2007. The Examiner has added the Lofberg et al. reference "to provide a link between myofilaments and their use in the evaluation of muscle damage."

Lofberg discloses use of various antibodies and detectable labels and markers to detect two different fragments of myosin heavy-chain, troponin I and troponin T for the purpose of assaying acute muscle damage, irreversible cardiac and skeletal muscle damage and reversible skeletal muscle damage from biological samples such as serum. Thus, like Wicks et al., Lofberg et al. is unrelated to detecting the presence of any of the myofilament protein modification products claimed.

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Thus, addition of the Lofberg et al. reference to the cited combination of references acknowledged by the Examiner not to render obvious the instant claimed invention in no way remedies the deficiencies in the teachings of the cited combination.

Claims of the instant application are drawn to a method for assessing cardiac or skeletal muscle damage in a subject by evaluating for the presence of **a post-translational modification of an intact myofilament protein, a post-translational modification of a degradation product of a myofilament protein or a post-translational modification of a protein-protein complex of myofilament proteins** selected from the group consisting of troponin I, troponin T, troponin C,  $\alpha$ -actinin and myosin light chain 1. Nowhere does Lofberg et al. nor any of the other cited references teach or suggest assessing cardiac or skeletal damage via detection of the presence of a myofilament protein modification product as claimed. Thus, this new combination of references, none of which is related to assessing cardiac or skeletal muscle damage via detection of the presence of a myofilament protein modification product, clearly provides no teaching or suggestion of all the claim limitations, no reasonable expectation of success with respect to the

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instant claimed invention, nor any motivation to arrive at the instant claimed invention, a method for assessing cardiac or skeletal muscle damage via detection of the presence of a myofilament protein modification product. Accordingly, the cited combination of references by Lofberg et al., Solaro et al., Lin et al. and Han et al. with or without Wicks et al. and/or Jideama et al. cannot render *prima facie* obvious the instant claims drawn to methods for assessing cardiac or skeletal muscle damage via detection of the presence of a myofilament protein modification product.

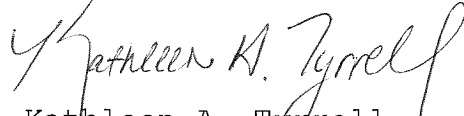
Withdrawal of these rejections under 35 U.S.C. 103(a) is therefore respectfully requested.

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**III. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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